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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,224	10/22/2001	John Bertin	07334-333001 / MPI2000-14	4988

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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/986,224	BERTIN ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11 and 18 drawn to an isolated nucleic acid molecule encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 16 or SEQ ID NO: 19, wherein the nucleic acid molecule comprises the nucleotide sequence of SEQ ID NO: 1, SEQ ID NO: 3; SEQ ID NO: 5, SEQ ID NO: 7, SEQ ID NO: 15, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 20, wherein the nucleic acid encoding a fusion protein; vector; host cells; method for producing a polypeptide; classified in class 435, subclass 69.1, 320.1, 252.3; class 536, subclass 23.5

Should Group I be elected, applicants are required to select one sequence of nucleic acid from claims 5-7, 9 and one sequence of amino acids from claims 1-4, 8 and 18.

II. Claims 12-16, drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 13, SEQ ID NO: 16 or SEQ ID NO: 19; fusion protein containing at least one pyrin domain, NBS domain, or LRR domain of SEQ ID NOs: 2, 4, 6, 8, 13, 16 or 19; a kit comprising a compound that binds to the polypeptide of claim 12; classified in class 530, subclass 350; class 435, subclass 69.7.

Should Group II be elected, applicants are required to select one amino acid sequence from claims 12-16.

III. Claim 17 and 20, drawn to an antibody that selectively binds to a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 13, SEQ ID NO: 16 or SEQ ID NO: 19; a

kit; classified in class 530, subclass 387.1+.

Should Group III be elected, applicants are required to select one amino acid sequence from claim 17.

IV. Claims 19, 22, 23, directed to finding a compound that binds to a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 13, SEQ ID NO: 16 or SEQ ID NO: 19; classified in class 530, subclass 350, 300; class 435, subclass 7.1.

Should Group IV be elected, applicants are required to select one amino acid sequence from claim 19, 22, 23.

V. Claim 21, drawn to a method for detecting the presence of a nucleic acid molecule in a sample by contacting the sample with a nucleic acid probe or primer which hybridizes to the nucleic acid molecule of SEQ ID NO: 1, SEQ ID NO: 3, SEQ ID NO: 5, SEQ ID NO: 7, SEQ ID NO: 12, SEQ ID NO: 14, SEQ ID NO: 15 SEQ ID NO: 17, SEQ ID NO: 18 or SEQ ID NO: 20; classified in class 536, subclass 23.1, 24.3, 24.33; class 435, subclass 6.

Should Group V be elected, applicants are required to select one amino acid sequence from claim 21.

VI. Claim, 24, directed to a use of a compound that modulates the activity of a polypeptide by contacting a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 13, SEQ ID NO: 16 or SEQ ID NO: 19 with a test compound; drawn to a method for modulating the activity of a polypeptide by contacting a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, SEQ ID NO: 13, SEQ ID NO: 16 or SEQ ID NO: 19, or a cell expressing the polypeptide with a compound that binds to the polypeptide in a sufficient concentration to modulate the activity of the polypeptide; classified in class 530, subclass 350, 300; class 435, subclass 7.1, 69.1.

Should Group VI be elected, applicants are required to select one amino acid sequence from claim 24.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the protein product can be made by another materially distinct processes, such as purification from the natural source or by chemical synthesis. Therefore, the inventions are distinct.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the Antibody of group III is a separate and distinct chemical entity from nucleic acid of group I. The nucleic acid of Group I does not encode the antibody of Group III and is not used for the practice of Group III. Therefore the inventions are distinct.

Invention I is unrelated to inventions IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of Group I is not used for the practice of detection method of group IV. Therefore the inventions are distinct.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group I can be used on another, materially distinct process, such as recombinant production of protein.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group I can be used on another, materially distinct process, such as hybridization assay.

The polypeptide of group II is related to the antibody of group III as being the antigen for the antibody. Although the protein and antibody are related, they are distinct inventions. The protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify a receptor. Further, the protein of Group II and the antibody of group III are structurally and functionally distinct molecules with different amino acids and different sequence.

Invention II is related to inventions IV and VI as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II has demonstrated different processes of use as set forth in the claims of Group IV and VI.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of group II is not necessary for the practice of invention of V. Therefore the inventions are distinct.

Invention III is related to inventions IV and VI as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of group III can be used on another, materially distinct process, such as affinity chromatography.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of III is not necessary for the practice of invention of V. Therefore inventions are distinct.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of IV and the method of V are directed to different ends. Method of IV detects a polypeptide and method of V detects a nucleic acid. Therefore the inventions are distinct.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of IV and VI are directed to different ends and different effect. Method of IV detects a polypeptide while method of VI detects a compound that binds to a polypeptide. Therefore the inventions are distinct.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the compound of VI is not necessary for the practice of invention V. Therefore the inventions are distinct.

The restriction requires for a selection of a single sequence of polynucleotide sequence and a single sequence of amino acid sequence because each sequence has a different chemical and physical property (See specification pages 8-17). For example the NBS-2 nucleic acid molecule has the nucleotide sequence shown in SEQ ID NO: 1, 12 and 14; and the NBS-2 protein has amino acid sequences of SEQ ID NO: 2 and 13 (page 8); while a NBS-3 nucleic acid molecule has the nucleotide sequence shown in SEQ ID NO: 3, 15 and 17 (page 9); and an isolated NBS-3 protein having an amino acid sequence of SEQ ID NO: 4 and 16 (page 10). In addition the invention also includes gene Pyrin-12/NBS4 and NBS-5 which have different nucleic acid and amino acid sequences (see Table 8), which are distinct from each other. Therefore, the use of each sequence in the method claims would have a different effect, for example use of a nucleic acid sequence from NBS-2 as a probe for the detection of nucleic acid in a sample may not detect the nucleic acid sequence of NBS-3 or NBS-4 or NBS-5, while use of

a polypeptide sequence of NBS-2 for identifying a compound that specifically binds to the polypeptide of NBS-2 may not detect the compounds that bind with the polypeptide of NBS-3 or NBS-4 or NBS-5. Therefore each sequence is distinct from the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Attorney Jack Brennan on December 15, 2003, to request an oral election to the above restriction requirement, but did not result in an election being made.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rita Mitra, Ph.D.
March 3, 2004

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